FDA Simultaneous Marketing ANPRM
Counts of Public Comment Submissions Coded By Issue

1 Comments unrelated to specific questions asked in FR notice - Drug approval *(1037)*
- **1.1** General comments on drug approval process *(35)*
- **1.2** Specific comments on drug approval process for Morning-after Pill/Plan B *(1337)*
  - **1.2.1** Approve for OTC for all *(16470)*
  - **1.2.2** Approve simultaneous marketing approach (market both OTC and Rx) *(158)*
  - **1.2.3** Maintain Rx only *(590)*
  - **1.2.4** Oppose drug product in any form *(147)*
- **1.3** Specific comments about other drug product *(9)*

2 Comments unrelated to specific questions asked in FR notice - FDA's general rulemaking process *(2470)*
- **2.1** Comments on time, manner, and nature of rulemaking process *(5999)*
- **2.2** Support ANPRM request for comments *(12)*
- **2.3** Oppose ANPRM request for comments *(473)*

3 Should FDA initiate a rulemaking regarding its interpretation of section 503(b)? [ANPRM Q 1.A.] *(0)*
- **3.1** Yes *(199)*
- **3.2** No *(249)*
- **3.3** FD&C Act and Amendments *(2)*
  - **3.3.1** FD&C Act requires rulemaking *(1)*
  - **3.3.2** FD&C Act is clear regarding when a drug should be prescription only *(18)*
  - **3.3.3** Other arguments related to FD&C Act *(17)*
- **3.4** Administrative Procedure Act (APA) arguments *(4)*
- **3.5** Supplemental New Drug Application (SNDA) and New Drug Application (NDA) regulations *(0)*
  - **3.5.1** SNDA/NDA regulatory arguments supporting rulemaking *(1)*
  - **3.5.2** SNDA/NDA regulatory arguments opposing rulemaking *(3)*
- **3.6** Court opinion legal arguments *(0)*
  - **3.6.1** Court case arguments supporting a rulemaking *(1)*
  - **3.6.2** Court case arguments opposing a rulemaking *(2)*
- **3.7** Other legal arguments *(0)*
  - **3.7.1** Other legal arguments supporting rulemaking *(4)*
  - **3.7.2** Other legal arguments opposing rulemaking *(4)*
- **3.8** Policy arguments *(0)*
  - **3.8.1** Rulemaking will improve future FDA decisions (clarity, consistency, efficiency) *(27)*
  - **3.8.2** Two-class system (OTC and Rx) not sufficient/behind-the-counter approach *(13)*
  - **3.8.3** Other policy arguments for initiating a rulemaking *(26)*

3.8.4 Interpretation is clear in present form *(25)*
3.8.5 Circumstances for OTC safety are case-specific *(17)*
3.8.6 Develop/update guidance as alternative for rulemaking *(2)*
3.8.7 Cost-benefit concerns regarding rulemaking *(8)*
3.8.8 Other policy arguments opposing a rulemaking *(26)*
3.9 Examples of previous FDA actions in allowing simultaneous marketing of Rx and OTC products *(0)*
3.9.1 Drug approval examples *(46)*
3.9.2 FDA guidance/other docs (e.g., 1999 Manual of Policy and Procedures) *(1)*
3.9.3 Veterinary drug policy *(1)*
3.9.4 Other examples *(2)*
3.10 Examples of FDA actions disallowing simultaneous marketing *(3)*
3.11 Miscellaneous arguments/discussions *(9)*

4 Is there significant confusion regarding interpretation of section 503(b) of the act? [ANPRM Q 1.B.] *(0)*
4.1 Yes *(181)*
4.2 No *(135)*
4.3 Arguments supporting significant confusion regarding FDA's interpretation *(0)*
4.3.1 FDA's interpretation of FD&C Act 505(b)(2) conflicts with interpretation of 503(b) *(1)*
4.3.2 Diverse industry and public opinion/reaction to ANPRM and statements re: FDA's authority *(9)*
4.3.3 Other legal arguments/conclusions supporting confusion re: FDA's interpretation *(6)*
4.3.4 Other policy arguments/statements supporting confusion re: FDA's interpretation *(20)*
4.4 Arguments indicating that little or no confusion exists *(0)*
4.4.1 Legal arguments that little or no confusion exists *(5)*
4.4.2 Policy arguments that little or no confusion exists *(15)*
4.5 Miscellaneous arguments/discussions *(14)*

5 Would rulemaking for clarification dispel confusion? [ANPRM Q 1.C.] *(6)*
5.1 Yes *(104)*
5.2 No *(141)*
5.3 Arguments that support concept that a rulemaking would provide clarification *(0)*
5.3.1 Legal arguments supporting rulemaking to dispel confusion *(4)*
5.3.2 Policy arguments supporting rulemaking to dispel confusion *(17)*
5.4 Arguments that a rulemaking would not provide clarification *(0)*
5.4.1 Legal arguments that rulemaking would not clarify *(2)*
5.4.2 Policy arguments that rulemaking would not clarify *(1)*
5.4.2.1 Guidance instead of rulemaking *(0)*
5.4.2.2 Other policy arguments *(8)*

5.4.3 There is no confusion, therefore rulemaking unnecessary *(10)*

5.5 Miscellaneous arguments/discussions *(17)*

6 If FDA limited sale of OTC product to sub-population, would FDA be able to enforce limitation as a matter of law? [ANPRM Q 2.A.] *(0)*

6.1 Yes *(174)*

6.2 No *(193)*

6.3 Legal/policy arguments that support/detail FDA's authority to enforce limitation on availability of OTC products by sub-population *(0)*

6.3.1 FD&C Act *(6)*

6.3.2 No laws prevent the policy *(3)*

6.3.3 Court cases *(0)*

6.3.4 Age limitations are in line with other meaningful differences *(10)*

6.3.5 Other legal/policy arguments *(16)*

6.4 Examples/precedents that support/detail FDA's authority to enforce limitation by sub-population *(0)*

6.4.1 Nicotine replacement therapy (e.g., Nicorette) *(78)*

6.4.2 Other examples *(1)*

6.5 Legal/policy arguments FDA does not have authority to enforce the limitation *(0)*

6.5.1 FDA's authority limited to drug safety, effectiveness/efficacy, and labeling *(94)*

6.5.2 Other FD&C Act arguments *(3)*

6.5.3 Court cases *(5)*

6.5.4 Other arguments *(35)*

6.6 Authority of other entities to enforce the limitation *(0)*

6.6.1 State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines) *(36)*

6.6.2 Congress *(5)*

6.6.3 Alcohol and tobacco enforcement *(204)*

6.6.4 Other entities *(3)*

6.7 Miscellaneous arguments/discussions *(14)*

7 Would FDA be able to enforce limitation to sub-population as practical matter? [ANPRM Q 2.B.] *(0)*

7.1 Yes *(149)*

7.2 No *(192)*

7.3 Actions FDA could take in order to enforce limitation of an OTC product to a sub-population *(0)*

7.3.1 Regulate product sponsor *(1)*

7.3.1.1 Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies) *(17)*

7.3.1.2 Require retailer, pharmacist, and consumer education programs *(8)*

7.3.1.3 Require risk management program *(2)*

7.3.1.4 Other product approval conditions *(3)*

7.3.2 Other FDA enforcement practices that it has the legal authority to put in place *(6)*

7.4 Other point-of-sale enforcement suggestions *(1)*

7.4.1 Implement "behind-the-counter" system (pharmacist distributed) *(92)*

7.4.2 Involve other authorities (e.g., states, state boards of pharmacies) *(7)*

7.4.3 Monitor compliance and enforcement / conduct random inspections *(16)*

7.4.4 Require identification for age *(152)*

7.4.5 Pursue criminal actions against violators *(22)*

7.4.6 Other actions *(31)*

7.5 FDA will be unable or it will be difficult to enforce as a practical matter *(0)*

7.5.1 FDA does not have authority to enforce limitation, therefore it cannot enforce as a practical matter *(6)*

7.5.2 Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place *(18)*

7.5.3 Actual compliance will be difficult/impossible/burdensome to achieve *(165)*

7.5.4 Other arguments *(13)*

7.6 Miscellaneous arguments/discussions *(10)*

8 Assuming legal to market both, may the prescription (Rx) and OTC products be legally sold in the same package? [ANPRM Q 3.A.] *(0)*

8.1 Yes *(183)*

8.2 No *(152)*

8.3 Legal arguments supporting one package label for Rx and OTC sales *(0)*

8.3.1 FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements) *(14)*

8.3.2 Do not need separate National Drug Code (NDC) numbers *(1)*

8.3.3 Court cases *(0)*

8.3.4 Other legal arguments supporting one package label *(6)*

8.4 Policy arguments supporting one package label for Rx and OTC sales *(0)*

8.4.1 Other policy arguments supporting one package label *(28)*

8.5 Legal arguments opposing one package for Rx and OTC sales *(5)*

8.5.1 FD&C Act - Legal differences between statutory requirements for Rx and OTC *(7)*

8.5.2 Court cases arguments opposing one package *(0)*

8.5.3 Need separate National Drug Code (NDC) numbers for billing *(3)*

8.5.4 Other legal arguments opposing one package *(8)*

8.6 Policy arguments opposing one package for Rx and OTC sales *(3)*

8.6.1 Single package contrary to meaningful difference standard *(2)*

8.6.2 Risk of medication errors or threats to patient safety *(26)*

8.6.3 Same packaging permits/encourages trading/swapping *(7)*

8.6.4 Other arguments opposing one package *(24)*

8.7 Examples of Rx and OTC labeling that is similar but with one or two differences – e.g., dosage/age distinction *(10)*

8.8 Examples of similar labeling of Rx and OTC products that are the same drug and dose, in the market place or previously marketed *(9)*
8.9 Miscellaneous arguments/discussions *(21)*

9 If they can be legally sold in same package, under what circumstances would it be inappropriate to do so? [ANPRM Q 3.B.] *(0)*
9.1 Circumstances in which it is inappropriate to distribute products in a single package *(0)*
9.1.1 Specific circumstances *(66)*
9.1.2 All circumstances (i.e., it's always inappropriate) *(73)*
9.2 Circumstance in which it is appropriate to distribute in single package *(0)*
9.2.1 Specific circumstances *(13)*
9.2.2 All circumstances (i.e., it's always appropriate, there are no inappropriate circumstances) *(222)*
9.3 Miscellaneous arguments/discussions *(12)*

10 Studies/data provided in comment *(22)*

11 Other miscellaneous comments unrelated to specific questions asked in FR notice *(1)*